

REMARKS

**Status of the Claims:**

Claims 11, 12, 18, 19, and 22 have been amended. Claim 8 has been cancelled. After amending the claims as set forth above, claims 1-3, 5, 6, 9-14, 17-25, 27, and 29-49 are now pending in this application.

**I. Claim Objections:**

**A. Claim 11**

Claim 11 is objected to because of the following informalities: line 2 contains an extra comma (,) after the word “material.”

Claim 11 has been amended in conformance with the Examiner’s suggestion. Accordingly, Applicant respectfully requests that the objection be withdrawn.

**B. Claim 12**

Claim 12 is objected to because of the following informalities: the second “material” at the end of the claim should be removed.

Claim 12 has been amended in conformance with the Examiner’s suggestion. Accordingly, Applicant respectfully requests that the objection be withdrawn.

**II. Claim Rejections – 35 U.S.C. § 112**

**A. Claim 8**

Claim 8 has been rejected under 35 U.S.C. 112 as failing to comply with the enablement requirement.

Claim 8 has been cancelled. Accordingly, Applicant requests the rejection be withdrawn.

**B. Claims 17-19**

Claims 17-19 have been rejected under 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 has been amended to be dependent on claim 6 upon which claim 17 depends. Claims 18 and 19 have been amended to be dependent on claim 6. Claim 6 provides antecedent basis for claims 17-19. Accordingly, Applicant requests the rejection be withdrawn.

**III. Claim Rejections – 35 U.S.C. § 103**

**A. Rejection over the Donohue Reference**

Claims 32, 1, 5, 8, 10, 11, 6, 9, 33-37, 43-48; 38, 21-25, 27, 29-31, 39-42, 49; 2, and 3 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al (WO 03/064909 A1) (Donohue). These rejections are respectfully traversed in view of the claims as amended herein.

**1. The Donahue Reference Does Not Describe Independent Claim 32.**

Independent claim 32 recites a tubing for conveying a fluidic media, the tubing comprising:

at least one layer of copolyester ether (COPE) material selected to be suitably compatible with the fluidic media, wherein the at least one layer of COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an innermost peripheral surface of the tubing.

(Similar features are found in independent claim(s) 2 and 38.)

Claim 32 is neither taught, suggested, nor rendered predictable by the Donohue and Moberg references, alone or in the combination suggested by the Examiner. In particular, claim

32 recites a tubing that includes, among other features, at least one layer of COPE material, the at least one layer of COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an innermost peripheral surface of the tubing.

Thus, at least one layer of COPE material has an outer surface that is an outer peripheral surface of the tubing and an inner surface that is an **innermost** peripheral surface of the tubing. As described, for example in paragraph [0037] of the pending application, such a tubing could include (but not limited to), for example, a tubing having a single layer, the single layer made of COPE material, or a tubing having an innermost layer and an outermost layer, each of the innermost layer and the outermost layer made of COPE material. The Donohue and Moberg references do not disclose or suggest a tubing, as recited in claim 32, including these features.

According to the Examiner, the Donohue reference discloses “a tubing (1) for conveying fluidic media comprising at least one layer of COPE (Paragraph [0016]) where the at least one layer of COPE comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface.” See p. 5 ll. 1-4 of the Office Action dated July 7, 2009 (*Office Action*).

As acknowledged by the Examiner, the Donohue reference does not “explicitly teach that the inner layer is comprised of COPE.” See p. 6 ll. 5-6 of *Office Action*. Accordingly, independent claim 32 is distinguished from the Donahue reference.

## **2. Omission of Donahue’s Intermediate and Inner Layers Is Not Obvious.**

The Examiner seeks to address the above-noted distinctions between claim 32 and the Donahue reference by arguing:

At the time of the invention, one having ordinary skill in the art of medical tubing would have recognized that COPE is a useful material in making medical grade

tubing without the use of harmful plasticizers (Paragraph [0016]) and would therefore find it obvious to make any and all layers of a medical tubing out of COPE.

*See* p. 6 ll. 6-9 of *Office Action*.

However, Applicant respectfully disagrees that it would have been obvious to make any and all layers of a medical tubing out of COPE. The Federal Circuit has noted that the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896 (CCPA 1966) (Claims at issue were directed to a printed sheet having a thin layer of erasable metal bonded directly to the sheet wherein said thin layer obscured the original print until removal by erasure. The prior art disclosed a similar printed sheet that further comprised an intermediate transparent and erasure-proof protecting layer that prevented erasure of the printing when the top layer was erased. The claims were found unobvious over the prior art because although the transparent layer of the prior art was eliminated, the function of the transparent layer was retained since appellant's metal layer could be erased without erasing the printed indicia.); MPEP 2144.04 II.B.

With respect to the Donahue reference, two embodiments of tubing (10) are disclosed: (i) a tubing having an outer layer of COPE (1), an intermediate layer of ethylene-vinyl acetate (2), and inner layer of polyurethane or polyethylene (3); and (ii) a tubing having an outer layer of COPE and an inner layer of polyurethane or polyethylene. *See, e.g.*, paras. [0009]-[0010] of the Donahue reference. Specifically, each of the tubings **at minimum** includes an inner layer of polyurethane or polyethylene **in addition to** the outer layer of COPE. Each of the tubings include such an inner layer so that the tubing can be flexible, have good fluid-flow

characteristics, and be compatible with the fluidic media contacting the inner layer. *See* para. [0004] of the Donahue reference. Thus, the inner layer of polyurethane or polyethylene provide the **function** of promoting flexibility of the tubing, providing good fluid-flow characteristics, and providing compatibility with the fluidic media.

In contrast, claim 32 is distinguished from tubings having does not recite such an inner layer. As mentioned, claim 32 includes an innermost layer (16) of a tubing (1) that is made of COPE material. A tubing having an innermost layer (16) of COPE material (i.e., omits an innermost layer of polyethylene or polyurethane) provides a **function** of being flexible, providing good fluid-flow characteristics, and providing compatibility with the fluidic media. *See, e.g.*, para. [0023]-[0025] of the pending application (noting that a COPE layer provides sufficient strength and flexibility characteristics); para. [0037] of the pending application (noting that inner layers of COPE, for example, can be selected to be stable and compatible with fluidic media in contact with the inner layer, or, for example, the inner layer of COPE can be treated to enhance stability and compatibility). Thus, claim 32 **omits** an innermost layer of polyethylene or polyurethane but **retains** the function of such a layer. Accordingly, it would not be obvious to form the innermost layer of COPE material, as recited in claim 32, in light of the tubings disclosed in the Donahue reference.

To establish a prima facie obviousness of a claim invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Because none of the references disclose or suggest the recited features, there can be no prima facie obviousness by seeking to combine these references. Thus, claim 32 is believed to be allowable.

**3. Advantages of Present Invention Shows Non-obviousness.**

Furthermore, the claimed tubing can provide significant advantages including:

- Simplification of manufacturing; and
- Improved manufacturing tolerance

For instance, a tubing having a **single** layer would be easier to extrude than a tubing of two or three different layers, which would have to be co-extruded or tri-extruded, respectively. In addition, a tubing made of a single material would require less tolerance as opposed to a tubing made of a plurality of layers each having they own unique dimensions. *See, e.g.*, paras. [0016]-[0017] of the Donahue reference (disclosing two different ranges for the COPE layer and the inner layer of polyurethane or polyethylene). Likewise, a tubing having an outermost layer and an innermost layer of COPE material, for example, would require less tolerance as one COPE layer could compensate for any manufacturing deficiencies of an other COPE layer.

In sum, because the tubing of claim 32 provides all of the above advantages, which are not disclosed or suggested in the Donahue reference, claim 32 is not obvious over the Donahue reference.

Claim 3 depends from claim 2 (directly or indirectly) and is believed to be allowable for at least the same reasons as claim 2 is believed to be allowable. Claims 1, 5, 6, 9-14, 17-20, 33-37, and 43-48 depend from claim 32 (directly or indirectly) and are believed to be allowable for at least the same reasons as claim 32 is believed to be allowable. Claims 21-25, 27, 29-31, 39-42, and 49 depend from claim 38 (directly or indirectly) and are believed to be allowable for at least the same reasons as claim 38 is believed to be allowable. Accordingly, the rejections of

claims 32, 1, 5, 10, 11, 6, 9, 33-37, 43-48; 21-25, 27, 29-31, 39-42, 49; 2, and 3 are respectfully traversed.

**B. Rejection over the Donohue and Moberg References**

Claims 12-14 and 17-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue and Moberg (USPN 6,248,093). These rejections are respectfully traversed in view of the claims as amended herein.

Claims 12-14 and 17-20 depend from claims 32 and 38 (directly or indirectly) and are believed to be allowable for at least the same reasons as claims 32 and 38 are believed to be allowable. Specifically, as discussed above, the Donohue reference does not disclose a tubing including at least one layer of COPE material having an outer surface that is an outer peripheral surface of the tubing and an inner surface that is an **innermost** peripheral surface of the tubing. According to the Examiner, the Moberg reference teaches “a drug delivery system (Fig. 1) combining a pump (101, 102, 103, 104), reservoir (105), and tubing (106) for the delivery of insulin (Col. 1, lines 14-16).” See p. 7 ll. 9-11 of *Office Action*. However, the Examiner’s argument does not address the recited feature lacking in the Donohue reference.

To establish a prima facie obviousness of a claim invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Because none of the references disclose or suggest the recited features, there can be no prima facie obviousness by seeking to combine these references. Thus, claims 12-14 and 17-20 are believed to be allowable. Accordingly, the rejections of claims 12-14 and 17-20 are respectfully traversed.

**IV. Conclusion:**

Applicant believes that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

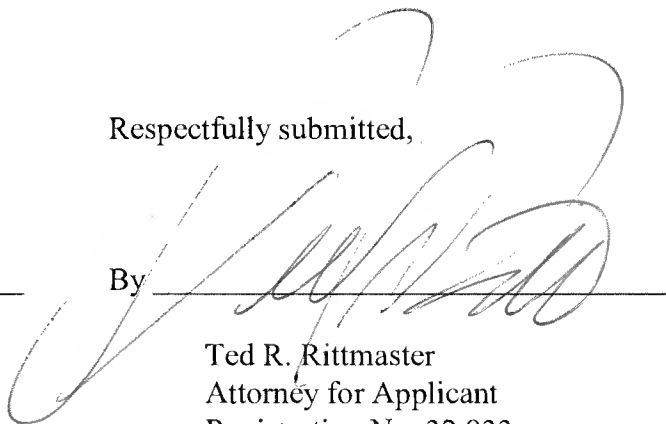
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10/7/09

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Respectfully submitted,

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